DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention [30Day-22-21HI]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Red Carpet Entry (RCE) Program Implementation Project to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on August 20, 2021 to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Red Carpet Entry Program Implementation Project - New - National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This information collection involves original, implementation research on the Red Carpet Entry (RCE) program to link persons with HIV to care within 72 hours of their diagnosis or their return to care after being out of care. Originally developed and implemented in Washington D.C. by Whitman Walker Health and the D.C. Department of Health's HIV/AIDS, Hepatitis, STD, and TB Administration, RCE has been shown to successfully and rapidly link people who tested HIV positive to an HIV care provider. Evaluations of RCE found that 70% of newly diagnosed people were linked to care within 72 hours of their HIV test. It was also shown to work for linking people who had fallen out of care with an HIV provider. An adapted version of RCE has also been shown to improve health outcomes among adolescents and youths in Kenya by quickly linking to care. The school-based program increased rates of linkage to care from 56.5% to 97.3% and three-month retention in care from 66.0% to 90.0%. Based on this, the CDC identified RCE as an evidence-informed structural intervention and included it in CDC's Compendium of Evidencebased Interventions (EBIs) and Best Practices for HIV Prevention.

Having an evidence-informed intervention like RCE that can be disseminated to the broader HIV health care community is important for several reasons: (1) Antiretroviral therapy (ART) is the best way to manage HIV and reduce transmission; (2) ART initiation is only possible when someone enters health care and then is ultimately retained in care; and (3) There are few existing evidenced-based structural interventions to support this process. This bias in the field of HIV interventions stems from a focus on individual behavior change interventions to prevent HIV infection. However, as new and effective treatments have emerged that reduce the likelihood of HIV transmission, HIV clinics and other healthcare settings have emerged as key contexts for HIV prevention by making sure that persons with HIV (PWH) have immediate access to ART. Therefore, the field has slowly shifted to understanding how providers and health systems can be encouraged to support PWH to reduce HIV.

This study will contribute to the field by creating tools to support clinics and healthcare settings that want to implement the RCE Program to link PWH to care. A toolkit will be created and tested via implementing RCE in two clinics, and lessons from the implementation of RCE will be used to update the toolkit. The final toolkit will be disseminated via CDC's website. Furthermore, because the study also evaluates the implementation strategies, outcomes, and context when RCE is being used, the study will be able to recommend what is needed to implement RCE with fidelity and success and incorporate these

insights into the toolkit. Finally, because tracking costs are also a part of the evaluation, clinics and health systems that are examining potential RCE adoption will have material information about what is needed to put RCE into practice. An understanding of the actual costs can provide important justification for program planners.

The results of this study will help CDC frame how best to disseminate the RCE Program to the broader HIV health care community. This is important because only federal agencies like CDC have the resources and infrastructure to broadly disseminate EBIs. Broad dissemination and uptake of EBIs like RCE can help move population rates of HIV suppression which would affect population transmission rates. Linkage to care, in an era of biomedical HIV prevention, is a prevention linchpin.

CDC requests OMB approval for an estimated 125 burden hours. There are no costs to respondents other than their time to participate.

Estimated Annualized Burden Hours

Type of	Form Name	Number of	Number of	Average
Respondents		Respondents	Responses	Burden
			per	per
			Respondent	Response
				(in
				hours)
RCE Clients	Screener	180	1	5/60
RCE	Staff Survey -	8	1	15/60
Implementation	Preparation			
Staff	Phase			
RCE	Staff Survey -	8	3	15/60
Implementation	Implementation			
Staff	Phase (months			
	1,3,5)			

RCE Implementation Staff	Staff Survey - Implementation Phase (months 2,4,6)	8	3	15/60
RCE Implementation Staff	Staff Interview Guide - Preparation Phase	8	1	1
RCE Implementation Staff	Staff Interview Guide - Implementation Phase (months 1,3,5)	8	3	30/60
RCE Implementation Staff	Staff Interview Guide - Implementation Phase (mos 2,4,6)	8	3	30/60
Clinic Leadership	Clinic Leadership Interview Guide	2	1	30/60
RCE Implementation Staff	Labor Cost Questionnaire	6	4	90/60
RCE Implementation Staff	Non-Labor Cost Questionnaire	2	9	90/60
RCE Implementation Staff	RCE Report Card	2	3	15/60

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